Health Care Professional from Dealer

Urgent Field Safety Notice

ProTime® 3 Cuvettes
Product Codes: PRO3-25 and PRO3-50
Reference Number IVD12.099 RAF 12-009
Return of Medical Device to the Supplier

Date

Attention: **Point-of-Care Coordinator, Oral Anticoagulation Clinic Director or Physician Office Manager**

Details on affected devices:
Please refer to the attached list of affected lot numbers.

Description of the problem:
The purpose of this letter is to provide important information regarding certain lots of ProTime3 cuvettes. An essential part of ITC's quality system is continuous product performance surveillance. During this surveillance ITC has determined that some ProTime3 Test Cuvettes (PRO3-25 and PRO3-50) within the specified lot range may recover lower than expected Prothrombin Time/International Normalized Ratio (PT/INR) results. The company's investigation into the product's performance identified increased imprecision in addition to an increased negative bias, the combination of which may manifest as lower than expected PT/INR test results.

Management of warfarin (Coumadin®) therapy may have been affected for patients whose dosing regimen was determined solely using results from the affected cuvette lots. A low bias in patient PT/INR results with ProTime3 cuvettes that goes undetected by a laboratory may contribute to sub-optimal warfarin therapy, which may lead to a hemorraghic event and the potential for serious injury in some patients. Four adverse event reports have been received by ITC; no permanent injuries or deaths were associated with these reports.

For patients tested with the affected ProTime3 lots, the PT/INR record should be reviewed and INR trends evaluated to determine if a repeat test is warranted. If a repeat test is required, ITC recommends that it be conducted either by using an ITC ProTime5 cuvette or a reference laboratory. It is advisable for you to conduct this review and follow up with your patients as soon as practicable. Please refer to the enclosed information for further information about the ProTime5 cuvettes.

ITC is implementing corrective actions to restore product performance.

ITC is conducting a voluntary medical device field safety corrective action for the affected lots which are listed on the attached table. This recall does not involve the ProTime instrument or the ProTime 5 cuvettes. Distribution records indicate that at least one box of an affected lot of ProTime3 cuvettes was shipped to your facility.

Please take the following actions:

1. Forward this communication to all those within your organization who need to be aware of this matter.
2. Check all inventory to determine if you have any of the affected lots listed in the attached table.
3. If you have any affected lots, stop using them and remove from inventory for return to your Dealer.
4. Complete the attached **Health Professional Account Tracking Form** and return it by fax, e-mail or mail to your Dealer. It is important that you complete the form whether or not you have remaining inventory of these lots. Returning the form promptly will ensure that you receive replacement product. Your Dealer will contact you to arrange for any inventory to be returned to them. You will receive replacements for all unused, returned product.

Please contact your Dealer or ITC Technical Support (Telephone 1-732-548-5700 Extension 4707 or email ProTime@itcmed.com) immediately if you become aware of an adverse event due to the use of affected ProTime3 cuvettes.

ITC has notified the relevant National Competent Authorities of this FSCA. The Authorized Representative is MDSS GmbH (Telephone: +49 511 6262 8630) or email info@MDSS.com.

We apologize for any inconvenience that this matter may cause.

Questions?	**If you have questions, please call your Dealer.**

20 Corporate Place South
Piscataway, NJ 08854 USA
Telephone +1-732-548-5700

Health Professional Account Tracking Form

ProTime3 Cuvettes

IVD12.099 RAF# 12-009

Please complete and return this form to your Dealer:

Customer Name _____

Customer Address _____
Street

_____
City Country Postal Code

Contact Name _____

Contact Phone Number _____

Fax Number _____ E-Mail Address _____

Please select all that apply:

☐ I have read and understand the attached letter.

☐ I do not have any of the affected lots.

☐ I have the following lots and amount of affected product in inventory:

Please circle the Item Number	ProTime3 Cuvette Lot No.	How many boxes do you have that have not been opened?	How many individual cuvettes do you have left in boxes that have been opened?
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			
ProTime3-25 or ProTime3-50			

☐ I have segregated and have stopped using the affected lots in inventory.

☐ I was not able to complete the actions provided in the letter because (please describe below):

_____

_____ _____
Signature Title

_____
Date

_____
Name (Print)

Fax, E-mail or Mail to your Dealer.